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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WARE, DEBORAH K

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

12/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,697	Applicant(s) ESTRADA GARCIA ET AL.	
	Examiner DEBBIE K. WARE	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/4/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 14-28 are presented for reconsideration on the merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 4, 2008, has been entered.

Response to Arguments

The amendments and corresponding arguments have been considered and the previous art rejection has been removed. However, new rejections based upon amendments and new art discovery have been set forth below in response to Applicants' newly amended claims and arguments.

Election/Restrictions

The restriction requirement of record has been withdrawn based upon the newly entered amendments and the claims have been rejoined on the record.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 4, 2008, was received. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-15 are rendered vague and indefinite for failing to clearly recite what the formulation contains, therefore. Further, claims 14-15 provide for the use of a formulation but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 16, 18, 26, 27 and 28 are rendered vague and indefinite for not clearly describing how the method is carried out in terms of how the administering step is performed. All other claims are rejected for being dependent upon rejected base claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14-15 are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an

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improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Hipskind et al (US 5773441), cited on enclosed PTO-892 Form.

Claims are drawn to a formulation with sequence His-D-Trp-Ala-Trp-D-Phe-Lys-NH₂. Also claims are drawn to a method for stimulating resistance to diseases in fish

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and crustaceans comprising administering to these animals an effective amount of GHRP-6 comprising SEQ ID NO: 1, which is His-D-Trp-Ala-Trp-D-Phe-Lys-NH₂.

Hipskind et al teach GHRP-6 comprising His-D-Trp-Ala-Trp-D-Phe-Lys-NH₂. Note col. 2, lines 29 and 35. Furthermore, artificial manipulation of growth hormone levels have been demonstrated to have significant therapeutic utility for disease states in humans. Also increase in lean muscle mass has been observed as well in animals, thus this makes animals stronger by increasing their protein to fat ratio. Note col. 1, lines 10-25. The GHRP-6 has been used in animal husbandry as an effective agent. The peptides are orally bioavailable, note col. 2, line 48. The reference teaches broadly several compounds which are useful for all types of animals including fish, note col. 3, line 63.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for the formulation and method for stimulating disease resistance in fish and crustaceans because the cited reference clearly teaches that the GHRP-6 having the identical sequence is useful for animal husbandry agents and a variety animals are disclosed to be treatable with a variety of compounds for affecting growth hormone levels in for example fish. Clearly Hipskind et al recognized the usage of GHRP-6 as claimed herein and to treat fish and crustaceans is clearly an obvious modification of the cited prior art. The reference teaches that fish are treatable and also recognizes the identical agent to be an effective animal husbandry agent. To orally, inject, or immerse an animal such as a fish or crustacean with this agent as claimed is well within the purview of an ordinary artisan.

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Also to vary the effective amounts is well within a manner of routine experimentation and one of skill would have expected successful results. To vary the protocol of treatment over several days is also well within the purview of an artisan, as is the encapsulation of feed for administering to fish and crustaceans. Also to select from tilapia or salmon species and the varied crustaceans of *Litopenaeus* and *Penaeus* is a matter of routine experimentation and one of skill would have expected successful results for treating all of these type of animals. In the absence of persuasive evidence to the contrary the claims are rendered prima facie obvious over the newly cited prior art rejection.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah K. Ware/
Deborah K. Ware
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